

### **REMARKS/ARGUMENTS**

An Office Action was mailed on January 22, 2007. This Office Action rejected all claims 1-20.

#### ***Summary of Telephone Interview***

Applicants' attorney, Philip Lee, and Examiner Michael William Kahelin held a telephone interview on April 26, 2007. Applicants' attorney thanks the Examiner for the opportunity to personally discuss Applicants' invention in order to permit clarification of Applicants' invention and to clarify Examiner's position for rejecting claims 1-20.

It was Applicants' position that U.S. 6,214,016, issued to Williams et al. (hereinafter "Williams") did not anticipate or make obvious any of Applicants' claims 1-20 because each of these claims included a limitation that the outer covering and inner core material were not movable with respect to each other in a final assembled stylet.

Applicants' attorney pointed out that, unlike Applicants' invention, the Williams device has an innermost member or stylet 46 which is retractable or movable relative to the inner tubular member 44 [See, Williams, Figures 5 and 6]. It is necessary that the innermost member 46 and inner tubular member 44 be movable in order to achieve the desired results of a curving entry.

The Examiner pointed out, however, that the innermost member 46 and inner tubular member 44 are not movable some of the time with respect to each other during the implantation procedure.

***Claims 1-20 rejected under 35 U.S.C. §112, first paragraph***

In the last Office Action, claims 1-20 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action states, "The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." [Office Action, page 2, paragraph 2.] "Examiner could find no support in the specification for the limitation "wherein the outer covering and inner core are not movable with respect to each other." [Office Action, page 2, paragraph 2.]

Applicants respectfully traverse this rejection. It is Applicants' position that there is a clear description in Applicants' application showing possession of the claimed invention.

Applicants' application discusses a specific manufacturing step of setting the outer covering over the inner core by heating and quenching. The core is first placed inside the tube, and the nitinol tube "can be drawn over the core by pulling the tube through a die." This drawing process compresses the nitinol tube over the core. In addition, [t]he drawn assembly is heated to a temperature above 400 C degrees for several minutes. Then the assembly is quickly quenched (commonly "quenching" is cooling with cold water or other cold liquid such as oil) or rapidly air cooled. This process sets the nitinol outer covering over the core. [See, Applicants' Specification, paragraph 52.] "To set" means to make the core immovable at all times relative to the outer covering.

Quenching of the hot outer covering causes contraction of metal outer covering to set firmly over the inner core. It is inherent that the end result from this heating and quenching procedure is to set the outer core over the inner core so that the two are immovable with respect to other at all times. If the inner core were intended to be capable of being withdrawn at some point from the outer covering, there would be no need to perform the additional manufacturing steps of heating and quenching.

Thus, support does exist in Applicants' specification and is positively described and, hence, the §112 rejection of each claim 1-20 is overcome.

***Claims 1, 2, 5-11, 14, 17 and 18 rejected under 35 U.S.C. §102(b), as anticipated by Williams.***

Claims 1, 2, 5-11, 14, 17 and 18 were rejected as anticipated by Williams. The Examiner stated that, "Further, the tube and inner core are not movable with respect to each other (when in the fixed state of column 3, lines 1-23)." [Office Action, p. 3, paragraph 5.]

Examiner has acknowledged in the April 26, 2007 interview that the Williams' innermost member 46 and inner tubular member 44 are in fact movable with respect to each other at some point, although the two pieces can be temporarily immovable during the lead implantation process. In order to further clarify the difference between Applicants' invention and Williams, each independent claim 1, 4 and 18 now include further language that the inner core and outer covering are immovable at all

times, and by dependency, dependent claims 2-3, 5-17, 19-20, also include this language.

With this further language “at all times” included in Applicants’ every claim, it is believed that Williams does not anticipate Applicants’ claims 1, 2, 5-11, 14, 17 and 18 because Williams is missing an element included in each of these claims, i.e., Williams does not have a device that has an inner core and outer covering that is immovable at all times.

***Claim 13 rejected under 35 U.S.C. §102(b) or §103(a); and  
Claims 3, 4 and 12 rejected under §103(a)***

Claim 13 was rejected under 35 U.S.C. §102(b) as anticipated by Williams or, alternatively, §103(a) as obvious over Williams. In addition, claims 3, 4 and 12 were rejected as obvious under 35 U.S.C. §103(a) as being unpatentable over Williams. Applicants traverse all of these rejections.

Applicants have already discussed why independent claim 1 is not anticipated by Williams because Williams teaches that the innermost member 46 and inner tubular member 44 must be movable at least sometimes. In contrast, the manufacturing method specified by Applicants clearly indicates that the inner core and outer covering must be immovable at all times. When a reference is missing an element of the claim, it cannot anticipate the claim. Claim 13 depends from claim 1 and, by this dependency, claim 13 is not anticipated by Williams. The §102(b) anticipation rejection of claim 13 is overcome.

With respect to the §103(a) obviousness rejections of claim 13 and, also, claims 3, 4 and 12, these rejections are traversed. Williams teaches away from Applicants' claim 1 because Williams suggests parts (innermost member 46 and inner tubular member 44) that at least temporarily must be movable relative to each other. When a reference teaches away from an element of a claim, that reference cannot be used to make obvious such a claim. **[See MPEP section 2145 X D., p. 2100-161, rev. 5, August 2006.]** Because claims 13, 3, 4 and 12 all depend on claim 1, which is not obvious in view of Williams, dependent claims 13, 3, 4 and 12, which now includes the limitation that the outer covering and inner core are immovable with respect to each other at all times, are each not obvious in view of Williams. As such, the obviousness rejections under Williams of claim 13, as well as claims 3, 4 and 12 are overcome.

***Claim 15, 19, and 20 rejected under 35 U.S.C. §103(a)***

Claims 15, 19 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Williams in view of Stoy et. al. (U.S. 5,217,026, hereinafter referred to as "Stoy"). Applicants respectfully traverse this rejection.

No combination of Williams and Stoy will yield Applicants' claims 15, 19 and 20 because each of these claims now includes a metal outer covering and inner core that are immovable with respect to each other at all times. In fact, Williams teaches away from Applicants' invention because it teaches that all parts are movable relative to each other, at least sometimes, whereas Applicants' outer covering and inner core are immovable with respect to each other at all times. The elements of a metal

outer covering and an inner core that are immovable with respect to each other at all times is missing in any combination of Williams and Stoy. In addition, Stoy teaches the outer covering is hydrogel, (not metal as in Applicants' invention) which hydrogel is used to reduce friction, not to impart composite mechanical properties, e.g. deformation, kink resistance or buckling strength (see Applicants' abstract; and Applicants' specification paragraph [0029]) to the device such as with Applicants' invention. Hence, Applicants' claims 15, 19 and 20 is not made obvious by any combination of Williams and Stoy.

Furthermore, one of ordinary skilled in the art would have no reason to combine the Stoy and Williams references. The purpose and functionality of each device described in Williams and Stoy are very different. Williams uses slidable moving elements that are not fixed relative to each other to provide a curved path through tissue. Stoy teaches a stylet with an outer covering of hydrogels to have a lubricious coating surface to avoid stylet or guidewire sticking. Separate, movable elements are important in Williams. In contrast, there are no movable elements in Stoy and the outer hydrogel covering is fixed or integral to the inner core [Stoy, column 4, line 5]. The two inventions of Williams and Stoy are conflicting in their function and their teaching and one skilled in the art would have no reason to combine the two references. **[See MPEP section 2145 X D., p. 2100-161, rev. 5, August 2006.]** For the foregoing reasons, the §103(a) obviousness rejection to claims 15, 19 and 20 is believed to be overcome.

We have not discussed the other separate reasons Applicants' dependent claims are not anticipated or made obvious by Williams itself or in combination with Stoy. Such other reasons may exist, but it is enough here to show that each of Applicants' claim 1-20 is neither anticipated nor made obvious by Williams itself or in

combination with Stoy because each of Applicants claims includes: an outer covering and inner core that are immovable with respect to each other at all times.

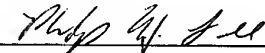
**A ONE-MONTH EXTENSION OF TIME IS REQUESTED**

With this Amendment D, a one-month extension of time is requested, making the due date for response to the Office Action (mailed January 22, 2007), **May 22, 2007**. Please charge the fee for this one-month extension, and any other required fees to **Deposit Account Number 50-0648**.

An early indication of allowability of pending claims 1-20 is respectfully requested. The Examiner is encouraged to telephone the undersigned to resolve any issues concerning this application.

Respectfully Submitted,

May 16, 2007  
Date

  
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